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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-488E]**

**Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2019**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final order.

**SUMMARY:** This final order establishes the initial 2019 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**DATES:** Valid [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Kathy L. Federico, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:**

**Legal Authority**

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine,

pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

## **Background**

The 2019 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured in the United States in 2019 to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

On August 20, 2018, the DEA published a notice titled “Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2019” in the *Federal Register*. 83 FR 42164. This notice proposed the 2019 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2019 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before September 19, 2018.

## **Comments Received**

The DEA received 48 comments from professional organizations, patients, associations, universities, Senators, State Attorneys General, a doctor, DEA registered

entities, and non-DEA entities. The comments included concerns about the quota process, shortages, prescriptions, diversion, marihuana, requests for a hearing, requests for increase in specific production quotas, and other comments that are outside the scope of the notice.

### **Quota Process**

There were eight commenters that expressed concerns about the quota process. Some of these commenters requested that the DEA consider information from the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) to determine the aggregate production quota. Other commenters stated that the DEA did not consider the factors contained in the Controlled Substances Quotas Final Rule published on July 16, 2018, 83 FR 32784, to determine the 2019 aggregate production quota.

The DEA has obtained and considered relevant information from the FDA. The information the DEA received included the observed and estimated domestic usage of 26 schedule II controlled substances, new drug applications and abbreviated drug application approvals, and clinical trials for schedule I and II controlled substances.

Regarding the Final Rule published on July 16, 2018, 83 FR 32784, the DEA amended the factors set forth in 21 CFR 1303.11 to be considered when setting the aggregate production quotas to include the extent of diversion of the controlled substances in each class, and relevant information obtained from the HHS, the FDA, the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), and the states.

The DEA has solicited the states and federal partners to obtain relevant information to be considered when setting the aggregate production quota pursuant to 21 CFR 1303.11

and this information will be considered for the 2019 proposed adjustments to the aggregate production quota. The DEA will continue to solicit information from the states for the 2020 aggregate production quotas and the years to follow.

However, the DEA is obligated to issue individual production and procurement quotas sufficiently in advance of the upcoming year to allow manufacturers to prepare for the legitimate needs of the United States. The DEA may not issue individual production and procurement quotas until the aggregate production quotas have been established. As a result of these obligations under the CSA, the DEA was not able to obtain and consider the amended factors set forth in Final Rule, 83 FR 32784, for the purpose of issuing the 2019 proposed aggregate production quota.

The DEA has a fluid process for setting quotas which allows the agency to make necessary quota adjustments. The process involves setting the proposed aggregate production quotas for a calendar year, and, following the review of any comments, the issuance of a Final Order to establish the aggregate production quota. Later in the process, the DEA issues a Proposed Adjustment to the aggregate production quota, and following the review of any comments, DEA issues a final order setting the Final Adjusted Aggregate Production Quotas. The DEA will consider the additional information received in the course of preparing proposed amendments and the final 2019 adjusted aggregate production quota.

### **Shortages**

There were 28 commenters that expressed concerns about the decrease in certain aggregate production quotas. These commenters alleged that decreases to the aggregate production quotas have resulted in a shortage of injectable opioid medications and

interfere with the treatment of patients. Some of these commenters also suggested that the DEA separate quotas for solid oral controlled substances and injectable controlled substances, and that DEA allow consideration by individual pharmaceutical dosage forms.

The DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet legitimate medical, scientific, and export needs of the United States. Although the DEA sets the aggregate production quota, it is possible that manufacturers' business practices may lead to a shortage of controlled substances at the consumer level, despite the adequacy of the aggregate production quota set by DEA. The aggregate production quotas are set by the DEA in a manner to include both injectable opioids and solid oral opioids in order to ensure that the estimated medical needs of the United States are met.

Notably, at the time of the proposed aggregate production quota, 21 U.S.C. 826(a) provided that "production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance." On October 24, 2018, the President signed into law the SUPPORT for Patients and Communities Act of 2018, (Pub. L. 115-271), which now allows but does not require the DEA to grant quotas in terms of dosage forms if the agency determines that doing so will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. DEA will be evaluating these issues over time.

Furthermore, the DEA and the FDA can coordinate efforts to prevent or alleviate drug shortages pursuant to 21 U.S.C. 826a(2). For example, the asserted domestic shortage of

injectable controlled substances was alleviated through the FDA and the DEA collaboration to get specific injectable controlled substances imported into the United States.

### **Transparency**

Two Senators submitted a joint comment supporting the DEA's efforts to address the opioid crisis, but expressed concerns that the aggregate production quota for schedule II opioids remains too high. These commenters also requested a transparent explanation of the analysis and specific considerations that the DEA considered when establishing the 2019 quotas for schedule II opioids.

The DEA continues to address the opioid crisis through initiatives such as the President's Safer Prescribing Plan, which seeks to reduce nationwide opioid prescription fills by one-third within three years. The DEA has observed a decline in the number of prescriptions written for schedule II opioids since 2014 and will continue to set aggregate production quotas to meet the medical needs of the United States while combating the opioid crisis.

In determining the aggregate production quota, the DEA took into account the data regarding the number of prescriptions that have been issued and an analysis of the factors as then set forth in 21 CFR 1303.11. The specific information that was obtained and considered included an analysis of sales data from databases such as Automation of Reports and Consolidated Orders System (ARCOS) and IQVIA; in addition to FDA forecasts and projections, historical total market sales data, products entering and exiting the market, expected product development, expected exports, inventory data, theft and loss data, and company forecasts. As a result, the final aggregate production quota for

several opioids are decreased from the proposed initial 2019 levels. These decreases take into account the combined efforts of the the DEA, the FDA, and the CDC enforcing regulations and issuing guidance documents as well as many states enacting prescription monitoring database programs to stem the opiate/opioid epidemic.

### **Quotas and Prescriptions**

Eleven State Attorneys General submitted a joint comment recognizing DEA's efforts to combat the opioid epidemic and expressed concerns about excessive quotas for opioids. These commenters also expressed concerns about overprescribing and referenced various studies. The referenced material cited in these comments also discuss patients who divert their prescriptions by sharing their prescriptions with others.

The DEA continues to address the opioid crisis through laws, regulations, and initiatives such as the Safer Prescribing Plan. The Safer Prescribing Plan seeks to reduce nationwide opioid prescription fills by one-third within three years. The DEA has observed a decline for certain prescriptions written for schedule II opioids since 2014 which can be attributed to federal and state government activities and interventions, including the implementation of Prescription Drug Monitoring Programs, enforcement of current regulations, and guidance documents such as the CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, March 2016. The DEA will continue to address the opioid crisis while ensuring an adequate and uninterrupted supply of controlled substances in order to meet the demand of legitimate medical, scientific, and export needs of the United States.

The DEA sets aggregate production quotas in a manner to ensure that all prescriptions that are authorized for legitimate medical purposes can be filled. Prescribers who are

authorized to dispense controlled substances are responsible for adhering to the laws and regulations set forth under the CSA, which requires doctors to only write prescriptions for legitimate medical needs. Any practitioner issuing an invalid prescription for controlled substances and any pharmacy filling such a prescription would be in violation of the CSA.

Upon review of the studies, DEA has determined that they are insufficient to support a reduction in the aggregate production quotas. The studies have found, with respect to a variety of medical procedures, that physicians prescribe more controlled substances for post-operative pain than the patients utilize. However, the DEA has concluded that while the referenced studies are concerning, they are insufficient to support a determination as to the level of overprescribing that occurs across the range of the medical procedures that are performed each year on a national basis.

#### **Including Diversion in Quotas**

Eleven State Attorneys General and three other commenters expressed concerns about DEA's ability to account for diversion when setting the aggregate production quotas.

The factors that DEA considers in setting the aggregate production quotas were amended in a Final Rule published on July 16, 2018, 83 FR 32784, to include the extent of any diversion of the controlled substances in the class, which will strengthen DEA's ability to reduce the likelihood of the diversion of controlled substances. When setting the established aggregate production quota, the DEA accounted for diversion by analyzing information such as, reports of controlled substance thefts and losses, and seizure data that are captured through internal DEA databases and will continue to do so when setting future aggregate production quotas. The DEA will also consider



information obtained from CMS, CDC, FDA, and the states which may include diversion data to be considered for the adjusted aggregate production quota.

### **Marihuana**

Seven commenters expressed their support for the increase in the production quota of marihuana. Three of those commenters expressed concerns about approval of applications for registration to manufacture (grow) marihuana. The DEA increased the production quota for marihuana based solely on increased usage projections for federally approved research projects. The DEA continues to review applications for registration and registers the number of bulk manufacturers of a controlled substance that is necessary to produce an adequate and uninterrupted supply.

### **Hearings**

Two commenters urged DEA to hold a public hearing. One of the commenters stated that the DEA should have a hearing to gather stakeholder feedback on how the DEA can help address the opioid epidemic while ensuring an adequate supply of opioids for clinically appropriate care. The second commenter stated that the DEA should hold a hearing to enable stakeholders to express their views about the proposed reductions.

Under the DEA regulations, the decision of whether to grant this type of a hearing on the issues raised by the commenters lies solely within the discretion of the Administrator. (21 CFR 1303.11(c) and 21 CFR 1303.13 (c)). I find that neither of the foregoing two requests presented any evidence that would lead me to conclude that a hearing is necessary or warranted. Therefore, I decline to order a hearing on the issues presented by the commenters.

### **Specific Quota for DEA-Registered Manufacturers**

The DEA received comments from four DEA-registered manufacturers regarding thirty-three different schedule I and II controlled substances. These commenters stated the proposed aggregate production quotas for 3-methyl fentanyl, 4-ANPP, acetyl fentanyl, acryl fentanyl, beta-hydroxythiofentanyl, butyl fentanyl, carfentanil, cyclopentyl fentanyl, cyclopropyl fentanyl, d-amphetamine (for sale), d,l-amphetamine, difenoxylate (for sale), fentanyl, fentanyl related substances, furanyl fentanyl, gamma hydroxybutyric acid, isobutyryl fentanyl, levorphanol, methoxyacetyl fentanyl, noroxymorphone (for conversion), ocfentanil, opium (powder), oxycodone (for sale), para-chloroisobutyryl fentanyl, para-fluorofentanyl, para-fluorobutyryl fentanyl, para-methoxybutyl fentanyl, remifentanil, sufentanil, tetrahydrofuranyl fentanyl, thebaine, U-47700, and valeryl fentanyl were potentially insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

The DEA has considered the comments for specific controlled substances and made adjustments as needed which are described below in the section titled Determination of 2019 Aggregate Production Quotas and Assessment of Annual Needs. The DEA did not receive any comments to the proposed established 2019 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

### **Out of Scope**

The DEA received seven comments which addressed issues that are outside the scope of this final order. The comments were general in nature and raised issues of specific medical illnesses, medical treatments, and medication costs and, therefore, are outside of

the scope of this Final Order, and do not impact the original analysis involved in establishing the 2019 aggregate production quotas.

### **Determination of 2019 Aggregate Production Quotas and Assessment of Annual Needs**

In determining the 2019 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors previously set forth in 21 CFR 1303.11 (as described above) and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the 2018 manufacturing quotas, current 2018 sales and inventories, anticipated 2019 export requirements, industrial use, additional applications for 2019 quotas, as well as information on research and product development requirements.

Based on all of the above, the Administrator is establishing the 2019 aggregate production quotas. These quotas are lower for codeine (for sale), codeine (for conversion), hydrocodone (for sale), morphine (for sale), and oxycodone (for sale); higher for cyclopentyl fentanyl, methoxyacetyl fentanyl, N-ethylpentylone (ephylone), para-methoxybutyryl fentanyl, and para-chloroisobutyryl fentanyl due to their temporarily controlled status; higher for amphetamine (for conversion) based on increased usage forecasted by the FDA and its use in the treatment of Attention Deficit Hyperactivity Disorder; higher for levorphanol based on manufacturers' ongoing product development activities necessary for the FDA approval process; and higher for opium powder and sufentanil based on manufacturers' projected exports.

Regarding 3-methylfentanyl, 4-ANPP, acetyl fentanyl, acryl fentanyl, beta-hydroxythiofentanyl, butyryl fentanyl, carfentanil, cyclopropyl fentanyl, d-amphetamine

(for sale), d,l-amphetamine, difenoxylate (for sale), fentanyl, fentanyl related substances, furanyl fentanyl, gamma hydroxybutyric acid, isobutyryl fentanyl, noroxymorphone (for conversion), ocfentanil, para-fluorofentanyl, para-fluorobutyryl fentanyl, remifentanil, tetrahydrofuranyl fentanyl, thebaine, U-47700, and valeryl fentanyl, the DEA has determined the proposed aggregate production quotas and assessment of annual needs are sufficient to provide for the 2019 estimated medical, scientific, research, industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these aggregate production quotas and assessment of annual needs at the same amounts as proposed.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2019 aggregate production quotas for the following schedule I and II controlled substances and the 2019 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Established 2019 Quotas
	(g)
<b>Schedule I</b>	
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	15
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl) indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole (AM-694)	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	30
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-(n)-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylon)	40
3,4-Methylenedioxypropylvalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboximide	25
4-Fluoroisobutyl fentanyl	30
4-FMC; Flephedrone	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl- $\alpha$ -pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25

1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide	25
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	30
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	30
5-Fluoro-PB-22; 5F-PB-22	20
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N-N-diisopropyltryptamine	25
5-Methoxy-N-N-dimethyltryptamine	25
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetyl Fentanyl	100
Acetyl- <i>alpha</i> -methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	2
Acryl Fentanyl	25
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH-7921	30
Allylprodine	2
Alphacetylmethadol	2
<i>alpha</i> -Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
<i>alpha</i> -Methylfentanyl	30
<i>alpha</i> -Methylthiofentanyl	30
<i>alpha</i> -Methyltryptamine (AMT)	25
<i>alpha</i> -Pyrrolidinobutiophenone ( $\alpha$ -PBP)	25
<i>alpha</i> -Pyrrolidinopentiophenone ( $\alpha$ -PVP)	25
Aminorex	25
Anileridine	20
APINACA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25
Benzylmorphine	30
Betacetylmethadol	2

<i>beta</i> -Hydroxy-3-methylfentanyl	30
<i>beta</i> -Hydroxyfentanyl	30
<i>beta</i> -Hydroxythiofentanyl	30
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Butylone	25
Butyryl Fentanyl	30
Cathinone	24
Codeine methylbromide	30
Codeine-N-oxide	192
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Desomorphine	25
Diampromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	8,225
Dihydromorphine	753,500
Dimethyltryptamine	50
Dipipanone	5
Etorphine	30
Fenethylline	30
Fentanyl related substances	25
Furanyl Fentanyl	30
<i>gamma</i> -Hydroxybutyric acid	33,417,000
Heroin	45
Hydromorphenol	40
Hydroxypethidine	2
Ibogaine	30
Isobutyryl Fentanyl	25
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthoyl))indole)	30
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Lysergic acid diethylamide (LSD)	40

MAB-CHMINACA; ADB-CHMINACA ( <i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1 <i>H</i> -indazole-3-carboxamide)	30
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
Methyl 2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3-methylbutanoate	25
Marihuana	2,450,000
Mecloqualone	30
Mescaline	25
Methaqualone	60
Methcathinone	25
Methoxyacetyl Fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
Naphthalen-1-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate	25
<i>N,N</i> -Dimethylamphetamine	25
Naphyrone	25
<i>N</i> -Ethyl-1-phenylcyclohexylamine	5
<i>N</i> -Ethyl-3-piperidyl benzilate	10
<i>N</i> -Ethylamphetamine	24
<i>N</i> -Ethylpentylone (ephylone)	30
<i>N</i> -Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	55
Normethadone	2
Normorphine	40
Ocfentanyl	25
Ortho-parafluorofentanyl	30
Para-chlorisobutyl Fentanyl	30
Para-flourobutyryl Fentanyl	25
Para-fluorofentanyl	25
Para-methoxybutyl Fentanyl	30
Parahexyl	5
PB-22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenomorphan	2



Pholcodine	5
Psilocybin	30
Psilocyn	50
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrocannabinols	384,460
Tetrahydrofuranyl fentanyl	5
Thiofentanyl	25
THJ-2201 ( [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	2
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
U-47700	30
Valeryl fentanyl	25
<b>Schedule II</b>	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,185,000
Alfentanil	6,200
Alphaprodine	2
Amobarbital	20,100
Amphetamine (for conversion)	12,700,000
Amphetamine (for sale)	42,400,000
Carfentanil	20
Cocaine	92,120
Codeine (for conversion)	12,900,000
Codeine (for sale)	36,114,260
Dextropropoxyphene	35
Dihydrocodeine	238,466
Dihydroetorphine	2
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	88,134
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	1,185,000
Glutethimide	2
Hydrocodone (for conversion)	5,000
Hydrocodone (for sale)	43,027,640

Hydromorphone	4,071,000
Isomethadone	30
Levo-alphaacetylmethadol (LAAM)	5
Levomethorphan	4,000
Levorphanol	38,000
Lisdexamfetamine	19,000,000
Meperidine	1,580,000
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	22,278,000
Methadone Intermediate	24,064,000
Methamphetamine	1,446,754
[846,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 564,000 grams for methamphetamine mostly for conversion to a schedule III product; and 36,754 grams for methamphetamine (for sale)]	
Methylphenidate	64,600,000
Morphine (for conversion)	4,089,000
Morphine (for sale)	29,353,676
Nabilone	62,000
Noroxymorphone (for conversion)	19,169,340
Noroxymorphone (for sale)	376,000
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	28,705,000
Oxycodone (for conversion)	2,081,000
Oxycodone (for sale)	79,596,606
Oxymorphone (for conversion)	24,525,540
Oxymorphone (for sale)	2,880,000
Pentobarbital	25,850,000
Phenazocine	5
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Racemethorphan	5
Racemorphan	5
Remifentanyl	3,000
Secobarbital	172,100
Sufentanyl	4,000
Tapentadol	18,388,280
Thebaine	84,600,000

<b>List I Chemicals</b>	
Ephedrine (for conversion)	25
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,100,000
Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	174,246,000

The Administrator also establishes aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2019 aggregate production quotas and assessment of annual needs as needed.

Dated: December 20, 2018

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Uttam Dhillon,  
*Acting Administrator.*

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